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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/520,230

02/02/2005

Sharat Singh

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70464

7590

02/25/2008

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EXAMINER

COUNTS, GARY W

ART UNIT

PAPER NUMBER

1641

MAIL DATE

DELIVERY MODE

02/25/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/520,230	Applicant(s) SINGH ET AL.	
	Examiner GARY W. COUNTS	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 1-9 and 23-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group II, claims 10-22 in the reply filed on July 25, 2007 is acknowledged.

Specification

2. The disclosure is objected to because of the following informalities: On page 19, line 19 the phrase "a this format" should be --this format--.

Appropriate correction is required.

3. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 10-22 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. A step of adding a cleavage-inducing reagent and a step of differentiating bound from unbound cells critical or essential to the practice of the

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invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

The specification on pages 16-19 teaches the addition of labeled target compounds (which bind to the cell surface antigen) or secondary labeled antibodies (which bind to antibodies bound to the cell surface antigen) with cleavage-inducing reagents to provide for cleavage of the cleavable-linkers on only those cell types bound to the antibodies, thus only releasing e-tags from these cell types. The specification also teaches capture specific cells with antibodies and then providing separation steps to separate bound from unbound cells and then the addition of a cleavable-inducing group to release only those e-tags from antibody bound cells. However, the invention as recited cannot work because if a cleavable-inducing group is not added in such a manner that only cells bound to an antibody are somehow differentiate from cells not bound to antibody or separated from cells not bound to antibodies, the cleavable-linkage would be cleaved in all cell types and the e-tags of all cells would be release and thus one could not identify a cell surface antigen specific to substantially only one of a plurality of cell types.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 10-22 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 is vague and indefinite because it is unclear what conditions causes cleavage of the cleavable linker. Does applicant intend that the temperature or pH of the assay system promotes cleavage? Does the binding of the antibody to the cell surface antigen cause cleavage and further how does one know that an antibody is bound to the cell surface antigen or not? Is some type of reagent present or added to the assay to cause cleavage? Further, if a reagent is added or present, it is unclear how the reagent would differentiate between unbound cells having cleavable linkages and cells having cleavable linkages bound to antibody. It appears that cleavable linkages would be cleaved regardless if bound or not. Please clarify. Applicant is reminded that a claim must stand on its own merits and that limitations from the specification are not read into the claims.

Claim 12, line 1 the recitation "short-lived" is a relative term which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 22 is vague and indefinite in relation to claim 10 because it is unclear how one can identify both a cell surface antigen and also identify an antibody which binds to the cell surface antigen without knowing the identity of either component in the assay? Please clarify.

Conclusion

8. No claims are allowed.

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9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Singh et al (US 6,949,347) disclose methods and compositions for determining one or more membrane associated analytes in a sample.

Singh et al (US 7,217,531) disclose methods and compositions for determining one or more membrane associated analytes in a sample.

Chan-Hui et al (US 7,105,308) disclose methods employing pairs of tagged probes and cleavage probes each of which binds specifically to a cell surface molecule.

Fodstad et al (US 6,893,881) discloses a method for detection of specific target cells in specialized or mixed cell population and solutions containing mixed cell populations.

Singh et al (US 7,255,999) disclose methods and compositions for analyzing proteins.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GARY W. COUNTS whose telephone number is (571)272-0817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ Gary W. Counts/
Examiner, Art Unit 1641

/Long V Le/
Supervisory Patent Examiner, Art Unit 1641